and most important step that causes properly usage of such products as well as preventing the side effects from abuse of such products and for highly consumed products such as sunscreen cares and depilatories.

PHP50

IMPLEMENTATION AND ASSESSMENT OF PERIODIC SAFETY UPDATE REPORTING SYSTEM AT TERTIARY CARE TEACHING HOSPITAL, KARNATAKA, INDIA: A DRUG CONTROLLER GENERAL OF INDIA INITIATIVE

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OBJECTIVES: To implement the PSUR system in all wards of hospital. Reporting of PSURs for all the running newly launched drugs since 2011 in hospital periodically to DCG (I), New Delhi and assessment of the PSUR system functioning in the hospital. **METHODS:** Prospective observational study. Drug safety reporting either manual or through online portal. Preparation and submission of PSURs as per Schedule Y of drugs and Cosmetics act, India. **RESULTS:** To implement the DCG (I) initiative PSUR program, one PSUR committee, one drug safety review panel and one Delphi panel for PSUR system assessment has been constituted. Drug safety reporting and assessment tools are prepared and validated. A manual reporting system of drug safety has been set up and one link on hospital intranet website will be very soon available for online drug safety reporting through each ward and departments of hospital. Necessary training on drug safety reporting is provided to all health care professionals. Online hospital information services are in use to track the prescription of these drugs to the in-patients and then, these patients are extensively followed for any drug related problem during their hospital stay. All the associated drug safety reports routed through wards to PSUR work station. The collected reports are assessed and coded using various scales, tools and softwares, e. g. Naranjo Scale, Hartwig severity scale and MedDRA coding software etc. PSUR system functioning in the hospital is assessed at regular time intervals through tool which is prepared and validated using Delphi technique. So far, since its inception two PSURs has been successfully submitted to DCG (I) at six months regular interval and third one is ready to report for next phase. **CONCLUSIONS:** The present pioneering hospital based PSUR setup will create an environment for healthy safety reporting and helps the regulatory authorities for safety related decisions.

PHP52

STUDY ON AUDIT AND CONTROL SYSTEM AND ITS CURRENT SITUATION

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OBJECTIVES: To study assessment and control the quality and the safety of hospitals in Mongolia. **METHODS:** The research has been conducted by cross-sectional study by collecting information according to the quantitative and qualitative method. **RESULTS:** In order to increase the quality and safety at the primary level hospitals the activity of special supporting (80.6%) and quality team control (66.7%) has been implemented, though, insufficient financing (33.3%) and professionals in quality control (19.4%) as well as special supporting activity has not been implemented (91.7%). The special supporting activity (87.0%) has been implemented ($p<0.05$) in the secondary level hospitals to increase the quality and safety, though, financing is insufficient (39.1%). The quality is conceptual idea, even though, this is a value that always could be felt and existed. The supporting activity (87.0%) and quality team (68.4%) are implemented ($p<0.05$) to develop the quality in the tertiary level hospitals, however, other activities that develop quality are not implemented. The participants in the study answered about the challenging issues are high at all hospital levels, such as long queue to receive health service (54.5%-76.5%), overload in the hospital (67.6%-81.8%) and referral between hospitals (45.5% -72.2%) as well as hospital professionals are susceptible to illness (31.3%-52.2%). **CONCLUSIONS:** Policy on quality and other related strategic documents are established 60-70% in the hospitals. Determination of health care and "determination of specialized health care standard through the diagnosis of the care" are insufficient at all level.

PHP53

ORGANIZATION POTENCY AND HUMAN RESOURCE

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OBJECTIVES: The purpose of the study was identifying the main problems of improving health care quality, organizational safety and human resource. **METHODS:** Questionnaire with 15 questions to study human resource potency. Financial statement balance of 2007 and 2012. Questionnaire with 12 questions to study medical equipments potency Observational lists of internal and external environment safety of the hospitals **RESULTS:** Totally 214 medical professionals were participated in the research: medical doctors 85 (39%), nurses 73 (34%), administration staff 16 (7%), and other staff 40 (19%). In 2007-2012 hospitals' funding were increased up to 80%, whereas the number of birth increased up to 121%, number of surgeries increased up to 26% and number of inpatient clients up to 19%. It's important to confirm the work position for medical equipment specialists and engineers according to the demands of medical equipment. **CONCLUSIONS:** It is concluded that there is increasing need of consideration on the number of nurses, doctors and other health professionals. The result showed that it is urgent to run policy to assess the employees' skills and supporting, appraising system should be open for everybody. Therefore 25% of the employees don't recognize the organization mission, security policy and the decision making system is highly relevant to money. Amount of funding has improved but it still inadequate. Funding is still inadequate even it has improved between 2007-2012. Domestic and foreign training is not enough for medical equipment specialists and engineers. Medical equipment technician's skills are not adequate. Medical professionals' knowledge about external and internal environment security are ineffective. Hospitals external conditions got worse to 27% and internal safety conditions worsen to 20%. Therefore there is a need to organize trainings for administrative staffs and workers.

PHP54

PHARMACOECONOMIC RESEARCH AND APPLICATION IN 10 ASIAN COUNTRIES BETWEEN 2003 AND 2013: A SYSTEMATIC REVIEW

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OBJECTIVES: To describe and analyze specific aspects of pharmacoeconomic research and application in 10 Asian countries in recent years from 2003 to 2013. **METHODS:** Our study concentrated on 10 Asian countries, including China, Indonesia, Japan, Malaysia, Philippines, Singapore, South Korea, Taiwan, Thailand and Vietnam. Literature was collected and reviewed systematically from United States National Library of Medicine- PubMed. Grey literature was also taken into account. After screening, a total of 268 pharmacoeconomic research articles and 38 pharmacoeconomic application studies were included. This review followed the Cochrane systematic review guidelines and PRISMA flow diagram. Publication was analyzed by regions, economic evaluation techniques used, drug groups analyzed. The status of these pharmacoeconomic studies was identified with options being: for scientific interest, undertaken to support reimbursement issues directly or performed in the framework of clinical guidelines or formularies. **RESULTS:** There is an increasing in the number of pharmacoeconomic studies in Asian countries in the later period (2008-2013) compared with the first five years considered (2003-2007). Most pharmacoeconomic studies were carried out in Japan (26%), China (22%), Thailand (15%), Taiwan (12%) and South Korea (10%). Cost-effectiveness analysis and cost-utility analysis were the most popular economic evaluation techniques used in 84% of total studies published. Antiinfectives for systemic use, antineoplastic and immunomodulating agents, nervous system and cardiovascular system drug groups were mostly researched and accounted for 41.79%, 19.78%, 10.45% and 8.21%, respectively. Status of pharmacoeconomics applications varied among countries. **CONCLUSIONS:** The number of pharmacoeconomic studies in Asia increased from 2008 onwards. The studies were mostly carried out in 5 specific countries (85% total) and concentrated to 4 specific drug groups. Types of pharmacoeconomics applications and research foci differ considerably amongst Asian countries.

PHP55

AN ANALYSIS OF PRICING PREMIUMS GRANTED THROUGH SUBMITTING LOCAL RCT AND PHARMACOECONOMICS DATA IN TAIWAN

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OBJECTIVES: The purpose of this study was to understand the drivers of the pricing premiums granted for submitting local RCT and / or local pharmacoeconomics (PE) data during the Taiwanese reimbursement assessment process. **METHODS:** The 11 products that submitted local RCT and / or local PE data in their reimbursement submission to the NHIA between January 2012 and March 2014 were analysed in this study. **RESULTS:** Of the 6 products that submitted local RCT data, 3 received the maximum 10% pricing premium for submitting these data. Abatacept was not granted any premium for not being a new molecule and benidipine hydrochloride was not granted any premium since its price comparator was an existing product that was already priced based on local data. Sorafenib has yet to receive a decision for the premium granted. Of the 7 products that submitted local PE data, 5 received a premium. 2 received a 1% and 2% premium respectively for submitting data with high uncertainty, 1 received a 2% premium for using inappropriate comparator dosage in the analysis, and 2 received a 5% premium for submitting data that were well accepted by the NHIA. 2 products did not receive any premium, as their data were considered to be incomplete or inappropriate. All of the submissions highlighted the product's cost-effectiveness against the comparator. **CONCLUSIONS:** A 10% pricing premium through local RCT data is likely achievable as long as the product with local RCT data is a new molecule whose comparator has not been priced based on its local data. On the other hand, achieving the maximum 10% pricing premium for submitting local PE data seems difficult to achieve; as of now, a 5% premium seems to be the maximum achievable. A premium as low as 1-2% is likely if there is any uncertainty in the data.

PHP56

REVIEW OF TAIWAN NHIA'S TWO-STAGE NEW DRUGS LISTING AND REIMBURSEMENT ASSESSMENTS (2013-FEB. 2014)

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OBJECTIVES: In Taiwan, the Second-Generation National Health Insurance (2G-NHI) Act was implemented since Jan. 1st, 2013. Thereafter, listing and reimbursement of new products are 2-stage assessments performed by the Expert Advisory Committee (EAC) and Pharmaceutical Benefits Reimbursement Scheme (PBRS) of National Health Insurance Administration (NHIA). EAC primarily evaluates clinical comparative effectiveness and safety of new products, and assessments are rated as Category 1 (substantial improvement), 2A (moderate improvement) or 2B (similar) compared to current standard therapy which are also used for pricing comparators. PBRS further appraises the EAC's suggestions and make final reimbursement recommendations. The objective of this study was to analyze the trends of the PBRS appraisals from Jan. 2013 to Feb. 2014 since implementation of the 2G-NHI Act. **METHODS:** A total of 33 new drugs underwent EAC assessments and PBRS appraisals were reviewed for their Categories. Further analysis was conducted to understand the trends based on the therapeutic indications and comparators. **RESULTS:** There were 21 new drugs granted reimbursement recommendations from PBRS joint meeting. Approximately 57% of them were rated as Category 2B, 38% as Category 2A, and only 5% as Category 1. A new trend revealed that Category 2B new drugs were easier to be listed and reimbursed. The only Category 1 new product is an orphan drug in western countries used to mobilize haematopoietic stem cells for autologous trans-

plantation purpose. Almost all Category 2A new drugs fulfilled the unmet medical needs for infection control, tocolytic therapy in preterm labor, or new mechanism for cardiovascular disease. **CONCLUSIONS:** Category 2B new drugs with less financial impact to NHI system seem easier to reach listing and reimbursement goal in the 2-stage assessments. Reasonable budget impact and cost-effectiveness analysis are as important as robust comparative effectiveness data for PBRS appraisals. There is a need for long-term observation and further analysis.

PHP57

AN ANALYSIS OF THE KEY VALUE DRIVERS FOR HTA ASSESSMENTS IN TAIWAN

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OBJECTIVES: The purpose of this study was to identify the main value drivers behind the innovation category designations (1, 2A, 2B) assigned during the Taiwanese reimbursement process. **METHODS:** All products assessed for reimbursement from January 2012 to March 2014 by the National Health Insurance Administration (NHIA) were considered in this analysis. The details of the assessments have been extracted from the NHIA meeting minutes and Center for Drug Evaluation (CDE) reports. **RESULTS:** Category 1 designations are given to drugs that show "substantial clinical improvement", Category 2A designations to drugs that exhibit "moderate improvement", and Category 2B designations to drugs that provide similar clinical value to comparators. Since 2012,94 of 113 products received positive decisions from the NHIA. 19 received Category 2A (26%), 51 received Category 2B (71%), while 2 received Category 1 (3%). Most Category 2B drugs were considered as alternative therapeutic options with similar efficacy (94%) to an existing product; others were considered to provide better clinical value but a larger budget impact or higher price (6%). Most Category 2A drugs were considered to provide additional efficacy, safety, or convenience over the comparator (53%). Of the 2 Category 1 products, plerixafor was rewarded for its curative potential in hematologic malignancies, as well as its potential reduction of hospitalisation costs; azacitidine was rewarded for being a first-in-class therapy for Myelodysplastic Syndrome. 22 of 94 products did not receive any category, as they were indication expansions. 17 of 113 assessed products received negative decisions due to their significant budget impact (59%) or lack of clinical benefit (41%). 2 out of 113 decisions are pending. **CONCLUSIONS:** Both clinical and economic considerations heavily drive the assessment outcomes in Taiwan. In order to achieve a positive assessment outcome in Taiwan, a product needs to provide a combination of favourable clinical and economic data.

PHP58

FROM REGULATORY APPROVAL TO SUBSIDISED PATIENT ACCESS IN THE ASIA-PACIFIC REGION: A COMPARISON OF SYSTEMS ACROSS AUSTRALIA, CHINA, JAPAN, KOREA, NEW ZEALAND, TAIWAN AND THAILAND

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OBJECTIVES: Pharmaceuticals can be marketed when regulatory approval has been obtained. However other barriers may need to be cleared before patients can gain access to subsidised medicines. In the Asia-Pacific region these subsidised systems are often government programmes and range from national tax funded schemes (Australian Pharmaceutical Benefits Schedule) through to coverage of a specific population (Thailand Social Security Scheme for office workers). Navigating these systems can be as simple as submitting a pricing application or as complex as a full scale societal health technology assessments. The aim of this study is to compare the processes and timings between regulatory approval and subsidised access to medicines across the Asia-Pacific region. **METHODS:** Reimbursement guidelines from seven different jurisdictions in the Asia-Pacific region were reviewed. Differences in processes and time from regulatory approval to subsidised access were captured between Australia, China, Japan, Korea, New Zealand, Taiwan and Thailand. **RESULTS:** Only Australia and Thailand allows evaluation of reimbursement in parallel with regulatory evaluation. Parallel processing has been discussed in Korea and Taiwan but has not been implemented. The time between regulatory approval and subsidised access differs across jurisdictions. In general additional processes such as health economic evaluation, pricing negotiation, budget approval and administration prolong time to subsidised access well beyond 6 months post regulatory approval. Japan is unique as a reimbursement price should be published within 60 days after regulatory approval. **CONCLUSIONS:** While most jurisdictions in the Asia-Pacific region differ in terms of regulatory and access approval processes all but one of the jurisdictions included in this study require a regulatory approval letter before reimbursement can be sought. Parallel processing can shorten time for patients to access new medicines however other factors such as health economic evaluation, pricing negotiation, budget approval and administration are also important.

PHP59

A COMPARISON OF ASIAN AND GLOBAL PHARMACEUTICAL PRICES USING AN EKS METHOD

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OBJECTIVES: The study aimed to determine the differences between Asian and Global Pharmaceutical prices **METHODS:** The indices were developed using the Fisher Elteto, Koves, Szulc (EKS) method. The EKS method is widely used by the Organisation for Economic Co-operation and Development (OECD) but has not yet been applied to pharmaceutical prices. IMS MIDAS data was used to estimate prices and sales volumes. In order to construct the indices, the products needed to be defined as like. The definition of like in this study was based on molecules which are deemed to deliver equivalent health outcomes. The price indices were developed for countries in World Health Organisation (WHO) regions. The analysis compares prices across 56 countries over the period from 2005 to 2011 and included 42 molecules which were sold in each country for the period. The countries were organised into the WHO regions. In total, around 1,000,000 unique national, product brands were accessed for the analysis. **RESULTS:** Pharmaceutical price indices vary substantially between regions. The Asian regions recorded the lowest prices. The indices were as follows: South-East Asian Region D 0.21; South-East Asian Region B 0.31; European Region B 0.37 Western Pacific Region A; 0.44 European Region A 0.45; African Region E 0.46; European Region C 0.49; Western Pacific Region B 0.51; Eastern Mediterranean Region D; 0.54; Region of the Americas D 0.87; Region of the Americas B 0.90; Eastern Mediterranean Region B 1.11. **CONCLUSIONS:** This is the largest exercise ever undertaken in comparing international pharmaceutical prices. It also employs a more robust method than previous studies. The analysis shows Asian region pharmaceutical prices are the lowest in the world.

PHP60

PRINCIPLES OF EXTERNAL PRICE REFERENCING SYSTEM – A REVIEW

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OBJECTIVES: Review existing literature to understand the prevalent external price referencing (EPR) systems and to audit for directionality of the current mechanisms against the components defined in WHO/HAI (World Health Organization/Health Action International) project on EPR. **METHODS:** English publications between October 2000 and March 2013 investigating EPR systems were identified through EBM Reviews – Cochrane Database of Systematic Reviews, NHS Economic Evaluation Database; Embase; and MEDLINE searches. Publications on EPR systems were analyzed in three relevant groups. Qualitative analysis was done to audit the directionality. **RESULTS:** 101 out of 598 articles were found to be relevant and were placed and allocated into three relevant focus groups - 43 general, 44 individual country, and 14 disease specific reference pricing articles. Regional distribution of publications was as follows: 49 RE (Region Europe), 12 Americas, and 15 Asia-Africa-Oceania. Number of publications over years was ranging from 3 to 10 with a significant peak in 2011 at 21.52 articles were found to have directionality against the components defined in WHO/HAI project, and the use of several approaches for setting the price was commonly discussed. Use of EPR was discussed for both patented and generic drugs. Publications showed directionality towards use of several approaches for EPR and were directing the use of EPR for both patented and generic drugs. With regards to type of price level used, ex-manufacturer price was the dominant option. The formula to derive the target price was directing towards average price. **CONCLUSIONS:** There is a growing trend towards increase in number of publications on EPR with lead from RE. A number of discussions around the components raised on WHO/HAI Project indicate that it is a useful tool to lay out options for ERP. Growing number of publications will provide more robust evidence for commonly used options of each component.

PHP61

ECONOMIC IMPACT OF NEW RURAL COOPERATIVE MEDICAL SCHEME IN CHINA

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OBJECTIVES: In 2003, China introduced a heavily subsidized voluntary health insurance program, the New Rural Cooperative Medical Scheme (NRCMS). This paper evaluates the effectiveness of the NRCMS by assessing its impact on health care utilization and out-of-pocket health expenditure. **METHODS:** We employ propensity score matching (PSM) with single difference and double difference based on data from China Health and Nutrition Survey (CHNS) from 1991 to 2009. To check the robustness of our results, we also use a bounding approach to test how strongly an invariant unobserved variable influences the selection process. For the out-of-pocket payments (OOP), a two-part model is used to correct for the large number of zero values and the skewness of the data. **RESULTS:** We find no evidence of an increase in the utilization of formal medical care and preventive services. There is a large, positive effect on the utilization of village clinics, and large, negative effects in town hospitals, county hospitals and city hospitals. For the two-part model of out-of-pocket (OOP) payments, we find a small, positive impact on the probability of positive OOP payments and a small, negative impact on the actual level of OOP payments. All the effects on the incidence of catastrophic medical payments based on different thresholds are insignificant. **CONCLUSIONS:** The results indicate that the NRCMS did not increase the overall utilization but directs people from high-level to low-level medical facilities. The substitution effect among different levels of facilities may be due to more generous reimbursement in low-level facilities. In addition, there is no reduction on the out-of-pocket medical payments or the incidence of catastrophic health payments. Therefore, the impact of NRCMS on increasing utilization and reducing financial risk is found to be limited. The lack of effectiveness may be attributed to a relatively low premium and shallow benefit coverage.

PHP62

REGULATORY APPROVAL TO PATIENT ACCESS, AN EVALUATION OF EU5 AND US NATIONAL TIMING DIFFERENCES

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OBJECTIVES: To examine the time between regulatory approval and launch/pricing and reimbursement (P&R) approval in the EU5 and US. **METHODS:** New molecular entities, formulations and combinations approved by the EMA between January 2009 and December 2013 were included in the analysis. FDA approval dates were retrieved and launch dates were gathered as follows: USA: Date wholesale acquisition cost was effective; UK/Germany: Product availability/introduction; France: P&R decision (Agrément collectivités/date published in Journal Officiel); Italy: First P&R Decree publication on Official Gazette; Spain: Date of commercialization; and Time comparison for general medicines vs. orphan and oncology indications was made including shifts over time. **RESULTS:** Time from approval to launch in the US aver-